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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: *18*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/981,559	Applicant(s) Wallach et al.
	Examiner David Romeo	Art Unit 1647
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<p>Period for Reply</p> <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
<p>Status</p> <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>4 May 2001</u></p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>		
<p>Disposition of Claims</p> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>29 and 36</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>29 and 36</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>		
<p>Application Papers</p> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<p>Priority under 35 U.S.C. § 119</p> <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some* c)<input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 		
<p>*See the attached detailed Office action for a list of the certified copies not received.</p>		
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p>		
<p>Attachment(s)</p> <p>15) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</p> <p>18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>20) <input type="checkbox"/> Other: _____</p>		

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/26/2001 (Paper No. 15) has been entered.
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2. Claims 29, 36 are pending and being examined.

Claim Rejections - 35 USC § 112

3. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 provides for the production of a molecule but the claim does not set forth any steps involved in the production it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this process is actually practiced.
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Claim Rejections - 35 USC § 101

4. Claims 29, 36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to or encompasses a method of screening for compounds that bind
5 the intracellular domain of 26 kDa TNF and/or modulate the phosphorylation thereof. The specification teaches phosphorylation of the serine residues of the intracellular domain of 26 kDa TNF. However, the biological significance of this phosphorylation is unknown. In the absence of a knowledge of the biological significance of the phosphorylation process there is no apparent specific and substantial asserted utility or a well established utility for either the screening process
10 or production of the compounds identified by the screening process. Further experimentation is necessary to attribute a utility to the claimed screening process. Evidence warranting further study is not equivalent to evidence showing the type of utility required by 35 U.S.C. 101. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that in context of the utility requirement "a patent is not a hunting license. It is not a reward for the search, but
15 compensation for its successful conclusion.").

Claims 29, 36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 112

5. Claims 29, 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to "producing" a molecule. However, the specification does not describe the production of any and all molecules with the desired characteristics. At best it might be obvious to the skilled artisan that it would be desirable to employ the materials and methods disclosed in attempt to produce such molecules. However, the 10 written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

6. Claims 29, 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to "producing" a molecule. However, the specification does not describe the production of any and all molecules with the desired characteristics. In the 15

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absence of this information the skilled artisan would have to resort to a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation is left to determine how to isolate and produce them. In view of the breadth of the claims, the limited
5 amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Conclusion

10 7. No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

15 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

20 
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

JULY 11, 2001